

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Andreas Bergmann	Group Art Unit: 1644
Serial No.:	10/516,618	Attorney Docket No.: 2582.020
Filed:	December 3, 2004	Confirmation No.: 7130
Title:	METHOD FOR DIAGNOSING SEPSIS BY DETERMINING ANTI-ASIALOGLANGLIOSIDE ANTIBODIES	

***CERTIFICATE OF ELECTRONIC FILING***

*I hereby certify that this correspondence is transmitted by electronic filing only to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on October 17, 2007. -*

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*Date of Signature: October 17, 2007*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT UNDER 37 C.F.R. §1.142

Dear Sir:

This is in response to the Office Action mailed September 18, 2007, in connection with the above-identified U.S. patent application. The one-month period for response expires on October 18, 2007. Accordingly, this response is timely filed.

Claims 1-13 were presented at the time of filing and are currently pending in the application. The Action of September 18, 2007 requires election under 35 U.S.C. 121 and 372 between three groups of claims:

Group I (claims 1-9), drawn to a method for the early diagnosis and diagnosis, for the prognosis and the assessment of the severity and for the therapy-accompanying assessment of the course of sepsis and sepsis-like systemic infections and for the estimation of the risk of a sepsis risk patient through the formation of a sepsis, characterized in that the presence and/or amount of anti-G<sub>M1</sub> antibodies and antibodies cross-reacting therewith in a biological fluid of a patient or sepsis risk patient are determined and conclusions are drawn from the presence and/or amount thereof with regard to the presence, the expected course, the severity or the success of a therapy of the inflammatory disease or sepsis or with regard to the risk of a sepsis risk patient.

Group II (claims 10-11), drawn to a method for the quality control of donor blood for medical purposes, in which the presence and/or amount of anti-G<sub>M1</sub> antibodies and antibodies cross-reacting therewith, in particular anti-G<sub>M1</sub> antibodies, are determined in a sample of the donor blood and, in the case of positive detection of such antibodies, the donor blood is rejected or is subjected to an affinity purification for removing the antibodies determined and is administered to a patient only after a subsequent further antibody determination with a negative result.

Group III (claims 12-13), drawn to a method for discovering and for detecting individual substances of mixtures of substances, which have structural properties which simulate ganglioside structures, in which individual substances or mixtures of substances to be investigated are tested in an assay system which is based on the binding of anti-ganglioside antibodies to a specific binder and the detection of bound antibodies, a competitive reduction of the antibody binding to the specific binder in the presence of the substance to be investigated being regarded as an indication of antibody-blocking properties of the substance or a potential risk of the substance owing to an antigen effect with initiation of the production of anti-G<sub>M1</sub> antibody or antibodies cross-reacting therewith in humans.

Applicants hereby elect the claims of Group I (claims 1-9). The election is made without traverse and without prejudice to Applicant's right to pursue the subject matter of the non-elected claims in one or more additional applications.

Applicants are further required to elect a single representative species for each of the following:

- 1) a single specific method preamble as recited in claim;
- 2) a single antibody isotype as recited in claim 2;
- 3) a single biological fluid as recited in claim 3;
- 4) a single specific binding assay as recited in claim 4;

5) a single specific further parameter or parameters for measurement in a single specific method as recited in claim 7; and

6) a single specific determination means as recited in claim 8.

Applicants hereby elect the following representative species:

- 1) a method for the diagnosis of sepsis (1-9);
- 2) IgG isotype (1 and 2);
- 3) blood fraction (1 and 3);
- 4) sandwich assay (1 and 4);
- 5) procalcitonin (1, 6 and 7);
- 6) immunochromatographic measuring apparatus (1 and 8).

Claims that read on each species are indicated in parentheses.

The Examiner is invited to contact Applicant's Attorney at the telephone number given below if any further questions arise in connection with this Application.

Respectfully submitted,



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Dated: October 17, 2007

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